SM

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/014,099 | 11/12/2001 | Ralf Kuhn | 100725-21/Kreisler 1097-K | 2636 |

27384 7590 03/15/2004

KURT BRISCOE
NORRIS, MCLAUGHLIN & MARCUS, P.A.
220 EAST 42ND STREET, 30TH FLOOR
NEW YORK, NY 10017

| EXAMINER | |
|---|---|
| CROUCH, DEBORAH | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | |

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/014,099 | KUHN ET AL. | |
| | Examiner | Art Unit | |
| | Deborah Crouch, Ph.D. | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, drawn to a fusion protein comprising a recombinase domain comprising a recombinase protein or a mutant thereof having a recombinase activity similar to that of the corresponding wild-type recombinase, and a signal peptide domain linked to said recombinase domain for the nuclear import of said fusion protein in eucaryotic cells, classified in class 435, subclass 196.

II. Claims 21-26 and 28-30, drawn to a DNA sequence encoding a fusion protein comprising a recombinase domain comprising a recombinase protein or a mutant thereof having a recombinase activity similar to that of the corresponding wild-type recombinase, and a signal peptide domain linked to said recombinase nuclear import of said fusion protein in eucaryotic cells, vectors, microorganisms, processing for preparing the fusion protein and cells, classified in class 536, subclass 23.4.

III. Claims 27 and 34, drawn to a method for recombining a DNA molecule containing recognition sequences for a recombinase protein in a eucaryotic cell or cell comprising contacting the cell with a recombinase fusion protein, classified in class 435, subclass 462.

IV. Claims 31-33, drawn to transgenic organism containing a DNA sequence coding for a recombinase fusion protein in its genome, classified in class 800, subclass 8.

V. Claim 34, drawn to a method for recombining DNA molecules of cells containing recombinase recognition sequences comprising contacting the cells with a DNA sequence encoding a recombinase fusion protein, classified in class 435, subclass 69.1.

VI. Claim 34, drawn to a method for recombining DNA molecules of an organism containing recombinase recognition sequences comprising contacting the cells with a recombinase fusion protein, classified in class 435, subclass 29.

VII. Claim 34, drawn to a method for recombining DNA molecules of an organism containing recombinase recognition sequences comprising supplying the organism with a

DNA sequence encoding a recombinase fusion protein or a vector comprising the DNA sequence, classified in class 514, subclass 44.

The inventions are distinct, each from the other because:

Inventions I and II are distinct because they are of separate uses. The fusion protein of invention I can be used to produce antibodies. The DNA sequence of group II can be used as a probe in hybridization assays.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the fusion protein of invention I can be used to produce antibodies.

Inventions I and IV are distinct because they are of separate uses. The fusion protein of invention I can be used to produce antibodies. The transgenic organism of invention III can be used to identify agents that affect recombination in vivo.

Invention I, and inventions V and VII are mutually exclusive and independent. The protein of invention I is not needed for the implementation of the methods of inventions V and VII, and vice-versa.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the fusion protein of invention I can be used to produce antibodies.

Inventions II and III are mutually exclusive and independent. The DNA sequence of invention I is not required for the implementation of the method of invention III, and vice-versa.

Inventions II and IV are mutually exclusive and independent. The DNA sequence of invention II can be used in a hybridization assay. The transgenic organism of invention IV can be used to determine the effect of compounds on recombination.

Inventions II and either invention V or VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA sequence of invention II can be used as a probe in hybridization assays.

Invention II and VI are mutually exclusive and independent. The nucleic acid of invention II is not needed to implement the method of invention VI, and vice-versa.

Inventions III and IV are mutually exclusive and independent. The method for recombination of invention III is not needed for the implementation of the transgenic organism of invention IV and vice-versa.

Invention III, and either invention V or VII are mutually exclusive and independent. The method of recombination of invention III requires a fusion protein to be added. Inventions V and VI requires the addition of a DNA sequence. The protocols for the implementation of inventions III and either V or VII are materially different and separate. Further, invention III is not required for the implementation of either invention V or VII, and vice-versa.

Invention III and invention VI are mutually exclusive and independent. The method of invention III requires the addition of a fusion protein to cells. The method of invention VI

requires the administration of a fusion protein to an organism. The protocols for the methods of invention III and VI are materially different and separate. Further, invention III is not required for the implementation of invention VI, and vice-versa.

Invention IV and inventions V-VII are mutually exclusive and independent. The transgenic organism of invention IV is not required for any of the methods of inventions V-VII, and vice-versa.

Inventions V and VII, and invention VI are mutually exclusive and independent. The methods of inventions V and VII required the introduction of a DNA sequence. The method of invention VI requires the introduction of a protein. The protocols for inventions V and VII are materially different and separate from the protocol for invention VI. Further, neither invention V nor VII is required for the implementation of invention VI, and vice-versa.

Inventions V and VII are mutually exclusive and independent. Invention V requires the introduction of a DNA sequence to a cell. Invention VII requires the introduction of a DNA sequence to an organism. The protocols for the methods of introduction are materially different and separate. Further, neither invention is required for the implementation of the other method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Further, because these inventions are distinct for the reasons given above and the search required for any of Groups I-VII is not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

March 9, 2004